

Activity levels in young patients with cemented total hip arthroplasty: a prospective observational actigraphic study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29269

Source

NTR

Brief title

ACTI-HIP

Health condition

Hip arthroplasty, hip osteoarthritis, activity level, actometer

Sponsors and support

Primary sponsor: Department of Orthopaedics, Radboud University Nijmegen Medical Centre

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The general average physical activity score, derived from the Actometer- data, and determined by the number of accelerations per 5-min periods will be determined during a 14-days period.

Secondary outcome

Self-reported daily Activity, Pain and Fatigue severity

Study description

Background summary

Total hip arthroplasty with impacted bone grafts show a tendency for better long-term prosthesis survival than hip arthroplasty patients without acetabular bone reconstruction. To determine whether activity levels play a role in prosthesis survival, a prospective observational cohort study was designed to determine activity levels in young primary cemented total hip arthroplasty patients under 50-years.

Physical activity levels are determined by actometer-data obtained during a 14-day period and by self-reported daily Activity, Pain and Fatigue severity questionnaire.

Study objective

The outcome of primary cemented total hip arthroplasty in young patients under 50-years implanted at our Department shows promising long-term prosthesis survival rates. However, many young patients have already an acetabular bone stock deficiency at surgery and they are the more demanding hips. In case of acetabular deficiency, these defects are reconstructed with impacted bone-grafts. Total hip arthroplasty with impacted bone grafts showed a tendency to even better long-term survival rates than hip arthroplasty without acetabular bone reconstruction, which is remarkable. Insight into the level of activity is necessary to determine if these good results are related to lower activity levels in the acetabular reconstruction group or related to the acetabular bone-grafting technique.

Study design

14-days period

Intervention

Prospective observational cohort study to determine activity levels in young primary cemented total hip arthroplasty patients under 50-years

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

1. Primary cemented total hip arthroplasty
2. Surgery at the Radboud University Nijmegen Medical Centre
3. Operated between 1988 and 2004
4. Younger than 50 years at time of hip surgery
5. Reconstructed with or without acetabular bone reconstruction

Controls:

1. Similar age (\pm 5 years) and gender

Exclusion criteria

1. Revision of primary hip prosthesis

2. Not able to walk

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion	
Date:	22-08-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1357
NTR-old	NTR1418
Other	St Radboud : UMCN-2008
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A